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| CHOI, FRANK I | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/721,131 | BASS, RALPH L. | |
| | Examiner | Art Unit | |
| | Frank I Choi | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *22-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 101/112*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-42 are rejected under 35 U.S.C. 101 because the claimed invention lacks credible utility.

The claimed method as is now amended is the alleviation of HIV infection by administration of sodium chloride to an HIV infected human. Despite the fact that more than a decade has past since the first cluster of cases of AIDS, neither a cure nor effective vaccine has been developed with treatment requiring compliance with multiple drug regimens (See Cecil Textbook of Medicine, Vol. 2 (21$^{st}$ Ed., 2000), pg. 1889). Further, it is generally accepted that the goal of anti-HIV therapy should ideally be to completely inhibit replication inhibition of replication by targeting reverse transcriptase and/or HIV protease (Id. at 1934). The specification does not appear to show any working examples which show effective treatment of HIV in mammals much less humans. The examples which are provided appear to be hypothetical statements of what would occur as opposed examples of effective treatment in actual patients. Further, Applicant's argued but not disclosed mechanism by which administration of sodium chloride results in reduction HIV appears to be unsupported by evidence showing that the disclosed effective levels of NaCl would be sufficient to alleviate

HIV. Applicant indicates that the administration should result in circulating levels of NaCl within the range of about 0.05 μM to about 1.0μM and that the extra amount of NaCl will disrupt the HIV virus. In Hrinda et al. (US Pat. 5,661,023) it is disclosed that NaCl concentrations as high as 1.4 M for prolonged periods, such as greater than 18 hours, only resulted in partial disassembling of HIV particles with dilution to 0.25M being sufficient to prevent the same (Hrinda et al., Column 8, lines 51-68, Column 9, lines 1-12). Thus, it appears that the effective amount of NaCl needed to disrupt the HIV virus far exceeds what is disclosed and claimed as being the effective therapeutic range as well as the level of NaCl which would be considered to be safe in humans (See generally Drug Facts and Comparisons (54th Ed., 2000), pg. 116; Martindale (30th Ed., 1993), pg. 862; Specification, Pgs. 12, 13). As such, in light of the above, it appears that the claimed alleviation of HIV infection in a human infected with HIV by administration of NaCl, while appearing to have specific and substantial utility, lacks credible utility.

Claims 22-42 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration orally, sublingually, buccally and combinations thereof, does not reasonable provide enablement for transdermal administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with said claim.

Transdermal administration is through the skin, however, the claimed method is administering to the upper gastro-intestinal tract which has no skin but mucous membranes. The specification does appear to show how a skilled artisan would administer sodium chloride in the upper GI tract transdermally when there is no skin in the upper GI tract. Further, it is uncertain how sufficient sodium chloride could be administered transdermally. See Dermatology Times (Nov. 1996), pp. S20 (no transdermal uptake of sodium chloride from salt baths). As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

Examiner had duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Actions and the further reasons below.

Applicant attempts to distinguish Sudilovsky by arguing that the Specification provides detailed prophetic examples of the claimed method. Contrary to Applicant's assertions, the specification in Sudilovsky was highly detailed (Sudilovsky at pg. 1705). Applicant asserts that there are no details on the amounts and frequency of the ACE inhibitor to be administered to the person. However, there is nothing in the Board's opinion which indicates that the Specification in Sudilovsky did not set forth amounts or frequency of the ACE inhibitor to administered to the person. The holding in Sudilovsky turns on the fact that the evidence provide was insufficient to show that the ACE inhibitors where effective against tardive dyskinesia. Id. Similarly, in this case, Applicant has provided prophetic examples, which regardless of their detail, are just that, "prophetic". Applicant has not provided sufficient evidence to show that administration of sodium chloride will be effective in alleviating HIV infection. As such, the arguments set forth amount to arguments of counsel which cannot overcome the enablement/utility rejection herein.

Applicant sets forth its theory as to how the invention works, i.e. that the concentration of sodium chloride will theoretically result in the rupturing of the HIV cell. Contrary to Applicant's assertion, Examiner has not quoted Applicant out of context. Applicant attempts to use the disclosure in Hrinda et al., which Examiner uses to refute Applicant's theory, to show that its theory is plausible. However, Applicant has made no showing that the amounts of sodium chloride used in Hrinda et al. either correspond to the Applicant's claimed amounts. In fact, as set forth in the prior Office Action, the minimum amounts in Hrinda et al. which result in partial disassembling of the HIV particles far exceed the claimed range, i.e. exposure to 1.4 M for eighteen hours versus about 0.05 microM to about 1.0 microM. Further as set forth in the prior Office Action, Merck brochure does appear to show that administration of sodium chloride as claimed would be effective in alleviating HIV infection or otherwise show that sodium chloride would act to disrupt the smaller HIV virus cells. As such, there is no evidence that one of ordinary skill in the art would expect from Hrinda et al. in view of the Merck brochure that administration of the claimed amounts of sodium chloride would be effective in alleviating HIV infection. Contrary to Applicant's arguments, Examiner has not ignored that Hrinda et al. discloses HIV in PBS. However, Applicant has not provided sufficient evidence which rebuts the finding that the claimed amounts of sodium chloride would not be effective in alleviating HIV infection. Applicant's unsupported conclusion that one of ordinary skill in the art would know that HIV in PBS would act differently from HIV attached to human CD4 T-cells does not appear to provide evidence that Applicant's invention works.

Applicant argues that there is a distinction between the enablement issue of 35 USC 112, 1st paragraph and the credible utility issue of 35 USC 101. However, the law is clear, if the

claimed invention lacks utility, the Specification cannot be said to have taught one of ordinary skill in the art to use the invention. See In Newman v. Quigg, 11 USPQ2d 1340, 1345 (CAFC 1989), cited by In re Cortright, the Court held that because the method did not produce the claimed result, following the teachings of the specification, the claimed invention was unpatentable under 35 U.S.C 101, for lack of utility, and 35 USC 112, first paragraph, for lack of enablement.

Applicant's reliance on In re Cortright is misplaced. The Court held that a disclosure that salves applied to the scalp penetrate the skin and reach the papilla or that chemicals affect hormones do not run counter to generally accepted scientific norms, thus a disclosure that the active agent, 8-hydroxy-quinoline sulfate, reached the papilla and offset lower levels of male hormones is not inherently suspect. In fact, In re Cortright supports the rejection in that, like the written disclosure in In re Cortright, the written disclosure in the present Application does not disclose that anyone observed the claimed result, i.e. alleviation of HIV, and the statements in the Specification do not reflect actual observations. Id. at pg. 1469. As such, there was evidence shown by actual results that the method in Cortright worked. Applicant continues to argue that there is no requirement for Applicant to prove how his invention works or provide actual working examples. However, Applicant must prove that the claimed method works.

In this case, the administration of sodium chloride to alleviate HIV infection is inherently suspect. Applicant argues that treating HIV infection was once considered an inherently unbelieveable undertaking, however, Applicant has provide no evidence of this assertion. Further, the issue is not whether treatment of HIV or baldness is considered inherently unbelievable but whether administration of sodium chloride to alleviate HIV infection is

inherently suspect. As indicated above, the recognized treatment of HIV is based on inhibition of replication by targeting reverse transcriptase and/or HIV protease and that treatment of HIV typically involves the use of multiple drug regimens. Applicant has not provided sufficient and credible evidence that administration of sodium chloride will alleviate HIV infection. Applicant submits 38 recent research studies, however, none address the use of sodium chloride in alleviating HIV infection or the effects of sodium chloride on HIV. Also, the issue of utility and enablement must be determined as of the filing date of the application, November 22, 2000. See In re Glass, 181 USPQ 31 (CCPA 1974); Curtis-Wright Corporation et al. v. Link Aviation, Inc., 124 USPQ 266, 285 (DC NNY 1959). As such, the submission of abstracts which were published after the filing date of the application cannot be used to support Applicant's argument for utility or enablement.

Applicant has withdrawn references 1-6, 10-19 as being published after the November 22, 2000 filing date of the application. Applicant argues that the remaining research studies 7-9, 20-38 have reported a correlation between a decrease in the ability of HIV-infected persons to inhibit HIV and the presence in HIV infected persons of a deficiency for various nutrients, such as sulfur, phosphorous, zinc, manganese, iron, chromium,iodine, magnesium, cobalt and selenium. It is uncertain how the references report a correlation between a decrease in the ability of HIV-infected persons to inhibit HIV and the presence of iodine deficiency when no reference appears to disclose iodine. It is uncertain how reference numbers 8,21,30,31 support this conclusion as the references provided contain a title but no abstract and the title does not appear to disclose any such correlation. Further there are deficiencies with the other references:

1. (2002) Does not disclose a causal correlation between selenium deficiency and alleviation of HIV infection.

2. (2002) Kupta et al. does not disclose a causal correlation between selenium deficiency and alleviation of HIV infection. Kupta et al. indicates that in reports from developed countries, low plasma selenium levels were associated with increased mortality in HIV-infected individuals but that further tests would be required to determine whether the association was causal.

3. (2002) Eley et al. does not disclose a causal correlation between selenium and copper deficiency and alleviation of HIV infection or even that many HIV-infected children have zinc and copper deficiencies. The study was of 60 HIV-infected children from economically deprived settings and only 20% had zinc deficiency and 25% had copper deficiency.

4. (2001) Does not disclose a causal correlation between copper and zinc deficiency and alleviation of HIV infection and in fact discloses that plasma levels of copper were not significantly associated with mortality.

5. (2001) Does not disclose a causal correlation between selenium deficiency and alleviation of HIV infection.

6. (2001) Does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection and in fact discloses that low dietary intake of zinc was common amongst both HIV uninfected and infected individuals and that zinc intakes were highest among participants in the intermediate but that the highest zinc intakes were amongst intermediate and late HIV infection stages.

7. (2000) Droege et al. does not disclose a causal correlation between sulfur deficiency and alleviation of HIV infection nor does it disclose that administration of sulfur will alleviate

HIV infection. In fact, it is disclosed that N-acetyl-cysteine was administered and that the effect on viral load was not consistent and that impairment of immunological functions in HIV patients results at least partly from cysteine deficiency and as indicated in reference 25 below administration of N-acetyl-cisteine did not alter viral load.

9. (1999) Discloses that out of manganese, iron, copper, chromium, cobalt, selenium and zinc, only zinc exhibited a reverse transcriptase activity in vitro in a dose-response fashion. In any case, no claim requires the presence of zinc and the Specification does not appear to disclose that zinc will alleviate the HIV infection or show that the amounts of zinc disclosed will alleviate HIV infection and references 32 and 35 disclose a correlation between zinc supplementation and poorer survival of HIV infected patients and progression to AIDS, respectfully.

10. (2001) Does not disclose a causal correlation between selenium and alleviation of HIV infection and in fact does not describe actual observations but a proposed study.

11. (2001) Does not disclose a causal correlation between zinc and alleviation of HIV infection and in fact does not describe actual observations but a proposed study. In any case, no claim requires the presence of zinc and the Specification does not appear to disclose that zinc will alleviate the HIV infection or show that the amounts of zinc disclosed will alleviate HIV infection and references 32 and 35 disclose a correlation between zinc supplementation and poorer survival of HIV infected patients and progression to AIDS, respectfully.

12. (2001) Does not disclose a causal correlation between selenium deficiency and alleviation of HIV infection and in fact does not describe actual observations but a proposed study.

13. (2001) Shor-Posner – Applicant argues that this reference shows administration of HIV –infected persons alleviated the HIV infection – actually, the abstract indicates that recent reports indicate that selenium is predictive of HIV-1 related prognosis and may have an important role in preventing HIV-1 replication but it does not disclose a causal correlation between selenium deficiency and alleviation of HIV infection and in fact is a proposal for a study to determine whether selenium could reduce viral load to slow HIV-1 disease progression in male and female drug users. In any case, no claim requires the presence of selenium and the Specification does not appear to disclose that selenium will alleviate the HIV infection or show that the amounts of selenium disclosed will alleviate HIV infection and as indicated below in reference 25 administration of sodium selenite did not alter viral load and in reference 9 above selenium does not decrease reverse transcriptase in a dose-response fashion.

14. (2002) Does not disclose a causal correlation between magnesium and zinc deficiency and alleviation of HIV infection and in fact discloses that increased intake, by itself, does not improve the health status of HIV infected patients.

15. (2002) Does not disclose a causal correlation between iron and zinc deficiency and alleviation of HIV infection and in fact discloses that median values for intake were adequate and that macronutrient but not micronutrient intake was statistically and inversely associated with decreasing CD4 cell counts.

16. (2002) Does not disclose a causal correlation between zinc and alleviation of HIV infection.

17. (2001) Does not disclose a causal correlation between zinc and alleviation of HIV infection.

18. (2001) Does not disclose a causal correlation between zinc and alleviation of HIV infection.

19. (2002) Discloses that statistically significant univariate associations were found between CD4(+) count and hematocrit, plasma magnesium concentration, and plasma zinc concentration and that independent variables that were significant joint predictors of CD4 (+) cell count in muliple regression analysis were hematocrit and plasma free choline and zinc concentration. It is concluded that compromised nutritional and antioxidant status begin early in the course of HIV-1 infection and may contribute to disease progression. However, the reference does not disclose a causal correlation between zinc, copper and magnesium deficiency and alleviation of HIV infection and the reference associates increased plasma levels of copper with late stage HIV infection. In any case, no claim requires the presence of zinc, copper or magnesium, the Specification does not appear to disclose that the same will alleviate the HIV infection or show that the amounts of the same disclosed will alleviate HIV infection and as indicated in references 32 and 34 zinc supplementation was associated with poorer survival of HIV infected patients and progression to AIDS, respectively.

20. (2000) Droege et al. does not disclose a causal correlation between sulfur deficiency and alleviation of HIV infection nor does it disclose that administration of sulfur will alleviate HIV infection. In fact, it is disclosed that N-acetyl-cysteine was administered and that the effect on viral load was not consistent and that impairment of immunological functions in HIV patients results at least partly from cysteine deficiency.

22. (2000) Does not disclose a causal correlation between supplementation of zinc or iron and alleviation of HIV infection.

23. (1999) Does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection. In any case, no claim requires the presence of zinc and the Specification does not appear to disclose that zinc will alleviate the HIV infection or show that the amounts of zinc disclosed will alleviate HIV infection and references 32 and 35 disclose a causal correlation between zinc supplementation and poorer survival of HIV infected patients and progression to AIDS, respectfully.

24. (1999) Does not disclose a causal correlation between any of the claimed nutrients and alleviation of HIV infection and in fact does not mention the claimed nutrients at all.

25. (1998) Does not disclose a causal correlation between sulfur or selenium deficiency and alleviation of HIV infection and in fact discloses that administration of N-acetylcysteine and sodium selenite did not affect viral load.

26. (1998) Does not disclose a causal correlation between selenium deficiency and alleviation of HIV infection. In any case, no claim requires the presence of selenium and the Specification does not appear to disclose that selenium will alleviate the HIV infection or show that the amounts of selenium disclosed will alleviate HIV infection and as indicated above in reference 25 administration of sodium selenite did not alter viral load and in reference 9 above selenium does not decrease reverse transcriptase in a dose-response fashion.

27. (1997) Does not disclose a causal correlation between zinc or selenium deficiency and alleviation of HIV infection and in fact discloses that there was no statistically significant difference in zinc or selenium levels amongst HIV infected and uninfected children.

28. (1997) Does not disclose a causal correlation between magnesium and alleviation of HIV infection.

29. (1997) Does not disclose a causal correlation between serum selenium levels and alleviation of HIV infection. In any case, no claim requires the presence of selenium and the Specification does not appear to disclose that selenium will alleviate the HIV infection or show that the amounts of selenium disclosed will alleviate HIV infection and as indicated above in reference 25 administration of sodium selenite did not alter viral load and in reference 9 above selenium does not decrease reverse transcriptase in a dose-response fashion.

32. (1996) Does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection and in fact discloses that any intake of zinc supplements was associated with poorer survival of HIV infected patients.

33. (1994) Does not disclose a causal correlation between chromium or phosphorus deficiency and alleviation of HIV infection.

34. (1996) Does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection and in fact discloses that intake of zinc supplements was associated progression to AIDS.

35. (1993) Discloses that HIV protease is inhibited in vitro by zinc ions at neutral pH but does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection.

36. (1993) Does not disclose a causal correlation between selenium deficiency and alleviation of HIV infection and in fact discloses that seroconvertors and noseroconvertors did not differ in preseroconversion levels of selenium.

37. (1990) Does not disclose a causal correlation between zinc deficiency and alleviation of HIV infection.

38. (1991) Does not disclose a causal correlation between dietary copper or zinc and alleviation of HIV infection and in fact discloses that neither dietary copper or zinc were associated with HIV-1 seropositivity or progression to AIDS.

In summary, Applicant has not shown with the submission of these 38 references that at the time of filing the present Application, that the claimed invention was enabled or had credible utility. The references fail to support the conclusion that one of ordinary skill in the art would conclude that the claims 22-42 had credible utility as none of the references disclose the use of sodium chloride to inhibit HIV or alleviate HIV infection. Applicant now attempts to argue that claim 28 has separate credible utility because of the presence of sodium chloride, potassium and up to 20% sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt or selenium. However, Applicant admits that sodium chloride and potassium are not addressed by the 38 references. Further, none of the 38 references show that supplementation of the one or more of sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt or selenium will alleviate HIV infection, i.e. that the blood will consistently test negative for the presence of HIV infection. Further, Applicant has not disclosed that sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt and/or selenium are added for the purpose of alleviating HIV infection and has not shown that the amounts disclosed would alleviate HIV infection. As such, one of ordinary skill in the art would be required to do undue experimentation in order use the claimed invention in that one of ordinary skill in the art would be required to determine whether and in what amounts supplementation of one or more of sulfur, phosphorus, zinc, manganese, iron, copper, chromium,

iodine, magnesium, cobalt or selenium in conjunction with sodium chloride and potassium would be effective in alleviating HIV infection.

Applicant argues that the issue does not rest on these references failing to show nutritional supplementation causes HIV to be inhibited, but rather the issue rests on these reference showing a correlation that suggests to a person of ordinary skill that is credible that supplementation could play a role in treatment of HIV. However, neither Applicant's claims nor the Specification disclose that that sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt or selenium are used to alleviate HIV infection which Applicant defines in the Specification as reducing viral titer. Applicant's invention is not merely treatment of a person infected with HIV but alleviation of HIV infection by reduction of HIV titer. As such the fact that sodium chloride is also a nutrient would not lend one of ordinary skill in the art to believe, even in light of the references cited, that sodium chloride would alleviate HIV infection. Applicant argues that zinc, selenium, copper and magnesium is recited in claim 28, however, claim 28 does not require that zinc, selenium, copper or magnesium be present. Even if they were present, Applicant has still made no showing that sodium chloride with or without the other nutrients would be effective in alleviating HIV infection by reduction of HIV titer.

With respect to the 112 rejection of claim 35, first paragraph for enabling transdermal adminstration. Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons of record and the further reasons below. In the first instance, transdermal administration is through the skin and the skin presents a effective barrier against absorption of sodium chloride. Applicant's reference to US 5,016,652 does not appear to overcome the rejection as US 5,016,652 does not disclose the transdermal administration of

sodium chloride in the amounts required by Applicant claimed invention or how a transdermal patch could be prepared to administer the same.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC
April 15, 2004

JOHN PAK
PRIMARY EXAMINER
GROUP 1600